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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/032,514	10/24/2001	Ping Niang Shen	1053-US	6834

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EXAMINER

FLOOD, MICHELE C

ART UNIT	PAPER NUMBER
1654	10

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
10/032,514

Applicant(s)
Shen et al.

Examiner
Michele Flood

Art Unit
1654



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Dec 2, 2002
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 33-43 is/are pending in the application.
- 4a) Of the above, claim(s) 39-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 33-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of:

- ☒ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. _____.
- ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 9 6) ☐ Other:

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DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendments filed on December 2, 2002. Acknowledgment is made of Applicant's cancellation of Claims 4-32, and newly added Claims 33-43.

Claims 1-3 and 33-43 are pending in the present application.

Election/Restriction

Applicant's election with traverse of Group I, Claims 1-3, in Paper No. 8 is acknowledged. The traversal is on the grounds that the Examiner has not provided any factual evidence that the restricted groups, Group I and Group II, are incapable of use together, that they have different modes of operation, different functions, or different effects. Without providing any factual evidence or explanation, Applicant argues, "Indeed, the composition and the method for identifying the composition are capable of use together and have connected modes of operation, function and effect." Finally, Applicant argues that no serious burden exists for the Examiner to search both Groups. This is not found persuasive for the reasons set forth clearly in the previous Office action, and repeated herein. In the instant case, the two different groups are directed to two different inventions. For instance the invention of Group I differs from the invention of Group II because the invention of Group I is directed to a composition comprising extracts from *Flos Lonicerae*, *Fructus Forsythiae* and *Radix Scutellariae*, whereas the invention of Group II is directed to a method for identifying a composition of *Flos Lonicerae*. These

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inventions are capable of separate manufacture, use or sale, as claimed, and are patentable (novel and unobvious) over each other (though they may be unpatentable because of the prior art) subjects.

Moreover, the two inventions above are independent and distinct each one from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches (as indicated by the different classification). The search for each of the above inventions is not co-extensive particularly with regard to the literature search. For instance, a search for the invention of Group I, that is the claimed composition would include a search for the instantly claimed constituents of the composition, whereas a search for the invention of Group II, that is the claimed method of identifying a composition would include a search of the instantly claimed method/process steps (fingerprint chromatography), ingredients (solvents, raw material, sample solution, chlorogenic acid, etc.), and experimental conditions thereof. Further a reference which would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application.

The requirement is still deemed proper and is therefore made **FINAL**.

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Newly submitted claims 33-38 reasonably read on the elected invention. However, newly submitted claims 39-43 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Independent Claim 1 is directed to a composition, whereas dependent Claims 39-43 are directed to assays and not a composition *per se*. Thus, claims 39-43 are drawn to several inventions which are patentably distinct and separate from the elected invention, and not required in the elected product for examination on the merits.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 39-43 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 1-3 and 33-38 are under examination.

Specification

The abstract of the disclosure is objected to because of the following minor informality: The abstract recites "*Flos Lonicerae Fructus Forsythiae* and *Radix Scutellariae*", in line 2. A comma should be placed between "*Flos Lonicerae*" and "*Fructus Forsythiae*" to place the abstract in proper grammatical form.

The disclosure is objected to because of the following informality: On page 8, lines 27-30, reference is made to "FIG. 8" without including an illustration of the drawing. Text referring

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to the omitted drawing should be deleted from the specification or other appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 and 33-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rendered vague and indefinite by the term "extracts" because this term, in and of itself, does not adequately delineate its metes and bounds. This term is best defined as a product-by-process since product-by-process claims are intended to define products which are otherwise difficult to define (and/or distinguish from the prior art). For example, are each of the extracts obtained via extraction with water, a polar solvent, a non-polar solvent, an acid or base, a squeezed extract, or something else? In addition, from what part(s) of the plant is the extract obtained? It is well accepted in the herbal art that extraction with one of various distinct solvents, as well as from particular parts of therapeutic plants, has a profound impact on the final product with respect to the presence, absence, amounts, and/or ratios of active ingredients therein and, thus, its ability to provide the desired functional effect(s) instantly claimed and/or disclosed. Since the extract itself is clearly essential to the claimed invention, the step(s) by which the

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claimed extract is obtained are also clearly essential and, therefore, must be recited in the claim language itself (i.e., as a product-by-process). Please note that although the claims are interpreted in light of the specification, critical limitations from the specification cannot be read into the claims (see, e.g., *In re Van Glens*, 988 F.2d 1181, 26 PSPG2d 1057 (Ded. Cir. 1991)). Accordingly, without the recitation of all these critical limitations as set forth above, the claims do not adequately define the instant invention.

The metes and bounds of Claim 1 are rendered uncertain by the phrase "effective amount of extracts" because it is uncertain as what is the functional intended use of the claimed composition. Thus, it is uncertain as to how to determine the "effective amount of the extracts" comprising the claimed composition. The lack of clarity makes the claim ambiguous.

An apparent typographical error appears in Claims 1 and 2. Each claim recites "*Flos Lonicerae Fructus Forsythiae* and *Radix Scutellariae*". A comma should be placed between "*Flos Lonicerae*" and "*Fructus Forsythiae*" to place the claims in proper grammatical form.

The metes and bounds of Claim 3 are made uncertain by the phrase "wherein the ratio of is approximately 1:2:1" because it is unclear as to the subject matter Applicant intends to direct the invention. It would appear that Applicant means that the ratio of the ingredients *Flos Lonicerae*, *Fructus Forsythiae* and *Radix Scutellariae* is approximately 1:2:1. Appropriate correction is required.

The metes and bounds of Claim 33 are made uncertain by the phrase "supercritical extract" because it is uncertain as to what solvent/gas is used in the making of the supercritical

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extract of *Flos Lonicerae* and *Fructus Forsythiae*. It is suggested that the limitations as set forth in the specification on page 22, lines 10-28, which detail a supercritical 'carbon dioxide' extract of *Flos Lonicerae* and *Fructus Forsythiae*, be inserted into the claim to add clarity to the instantly claimed invention.

Claims 34-36 recite the limitation "wherein said constituents". There is insufficient antecedent basis for this limitation in the claims.

Claim 37 recites the limitation "wherein virus" in line 1. There is insufficient antecedent basis for this limitation in the claim.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 37 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by

Houghton et al. (U).

Applicant claims a composition comprising effective amount of extracts from *Flos Lonicerae*, *Fructus Forsythiae* and *Radix Scutellariae* and a suitable carrier. Applicant further claims an antiviral and antibacterial pharmaceutical comprising effective amount of extracts from *Flos Lonicerae*, *Fructus Forsythiae* and *Radix Scutellariae* and a pharmaceutically acceptable carrier. Applicant further claims an antibacterial composition of claim 1. It appears that Applicant further claims the composition of claim 2, wherein the antiviral and antibacterial pharmaceutical composition is effective against a virus selected from the group consisting of herpes I virus, herpes II virus, influenza virus, parainfluenza virus, and the Human immunodeficiency virus. Applicant further claims an antibacterial composition of claim 1.

Houghton teaches the Chinese herbal mixture 'Aden-I', which comprises aqueous extracts of *Flos Lonicerae*, *Fructus Forsythiae* and *Radix Scutellariae* and a suitable pharmaceutical carrier, e.g., water. See page 384, Column 2, lines 11. Houghton shows that

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'Aden-I' has both an antibacterial and antiviral effect. For example, Houghton teaches that 'Aden-I' has antiviral effect against the influenza virus.

The reference anticipates the claimed subject matter.

Claims 1-3 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Matsuse et al. (V).

Applicant's claimed invention of Claims 1-2 and 38 was set forth above. It appears that Applicant further claims a composition of claim 1 or 2, wherein the ratio of the effective amount of *Flos Lonicerae*, *Fructus Forsythiae* and *Radix Scutellariae* is approximately 1:2:1.

Matsuse teaches a composition (Shuang Huang Lian) comprising the extracts of the flowers of *Lonicera japonica* THUNB. (*Flos Lonicerae*), the roots of *Scutellaria baicalensis* GEORGI (*Radix Scutellariae*), and the fruits of *Forsythia suspensa* VAHL. (*Fructus Forsythiae*) in the form of an intravenous infusion. On page 52, Column 1, lines 7-14, Matsuse teaches that the composition is useful for the treatment of antibiotic-resistant microorganisms. Matsuse further demonstrates that the referenced composition comprising *Flos Lonicerae* (43.5 g), *Fructus Forsythiae* (102 g), and *Radix Scutellariae* (35 g) suppresses the secretion of hepatitis B virus surface antigen (HBsAg) without cytotoxicity. Thus, the amounts of the plant extracts comprising the Matsuse' composition constitute a ratio of approximately 1:2:1.

The reference anticipates the claimed subject matter.

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Claims 1-3 and 37-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Xu (N).

Applicant's claimed invention was set forth above.

On page 2, lines 14-20, Xu teaches composition comprising extracts of *Flos Lonicerae*, *Fructus Forsythiae* and *Radix Scutellariae* having antiviral and antibacterial activity. On page 16, lines 6-12, the referenced composition is taught to effective against parainfluenza virus types 1, 2, 3 and 4. On page 26, in "EXAMPLE 2", Xu teaches a composition comprising 0.25 g *Radix Scutellariae*, 0.25 g *Flos Lonicerae*, and 0.5 g *Fructus Forsythiae* (1:2:1).

The reference anticipates the claimed subject matter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is (703) 308-9432. The examiner can normally be reached on Monday through Friday from 7:15 am to 3:45 pm. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196 or the Supervisory Patent Examiner, Brenda Brumback whose telephone number is (703) 306-3220.

Michele C. Flood

MCF

January 29, 2003